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(b) *Sponsors*. (1) See No. 054771 in § 510.600(c) of this chapter for use as in paragraphs (c)(1), (c)(2)(i), (c)(2)(ii), and (c)(3) of this section.

(2) See No. 017135 for use of the 4 percent product as in paragraph (c)(2)(iv) of this section.

(c) *Conditions of use*—(1) *Amount*. Hold container about 6 to 12 inches from the eye or affected area and apply only enough powder to impart a light yellow color.

(2) *Indications of use*—(i) *Dogs*. For treatment or prevention of bacterial infection of superficial wounds, abrasions, lacerations, and pyogenic dermatitis.

(ii) *Horses*. For treatment or prevention of bacterial infection of superficial wounds, abrasions, lacerations, and following firing (heat or electrocautery).

(iii) [Reserved]

(iv) *Horses and ponies*. For treatment or prevention of bacterial infection of superficial wounds, abrasions, and lacerations caused by *Staphylococcus aureus*, *Streptococcus spp.* and *Proteus spp.* sensitive to furazolidone.

(3) *Limitations*. For topical application in horses, ponies, and dogs: Clean affected area thoroughly, apply drug once or twice daily, and repeat treatment as required. Use only as recommended by a veterinarian in treatment of puncture wounds, wounds requiring surgical debridement or suturing, those of a chronic nature involving proud flesh, generalized and chronic infections of the skin, and those skin conditions associated with intense itching. If redness, irritation, or swelling persists or increases, discontinue use and consult a veterinarian. Do not use in horses intended for human consumption.

[45 FR 49543, July 25, 1980, as amended at 50 FR 30153, July 24, 1985; 56 FR 50653, Oct. 8, 1991; 57 FR 31314, July 15, 1992; 60 FR 55659, Nov. 2, 1995; 65 FR 41588, July 6, 2000; 79 FR 10969, Feb. 27, 2014]

§ 524.1044 Gentamicin ophthalmic and topical dosage forms.

§ 524.1044a Gentamicin ophthalmic solution.

(a) *Specifications*. Each milliliter of sterile aqueous solution contains gentamicin sulfate equivalent to 3 milligrams of gentamicin.

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(b) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) The drug is used in dogs and cats for the topical treatment of infections of the conjunctiva caused by susceptible bacteria.

(2) Administer 1 or 2 drops into the conjunctival sac 2 to 4 times a day.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[41 FR 14189, Apr. 2, 1976, as amended at 52 FR 7832, Mar. 13, 1987]

§ 524.1044b Gentamicin and betamethasone otic solution.

(a) *Specifications*. Each milliliter of solution contains gentamicin sulfate equivalent to 3 milligrams (mg) gentamicin base and betamethasone valerate equivalent to 1 mg betamethasone alcohol.

(b) *Sponsors*. See Nos. 000061 and 054925 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amounts and indications for use*—(i) For the treatment of acute and chronic otitis externa caused by bacteria sensitive to gentamicin in dogs, instill three to eight drops of solution into the ear canal twice daily for 7 to 14 days.

(ii) For the treatment of infected superficial lesions caused by bacteria sensitive to gentamicin in dogs and cats, apply a sufficient amount of the drug to cover the treatment area twice daily for 7 to 14 days.

(2) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[71 FR 13542, Mar. 16, 2006]

§ 524.1044c Gentamicin ophthalmic ointment.

(a) *Specifications*. Each gram of ointment contains gentamicin sulfate equivalent to 3 milligrams of gentamicin.

(b) *Sponsors*. See Nos. 000061 and 043264 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount*. Apply approximately a 1/2-inch strip to the affected eye 2 to 4 times a day.

(2) *Indications for use*. For treatment of conjunctivitis caused by susceptible bacteria.

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(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[69 FR 47363, Aug. 5, 2004, as amended at 77 FR 64717, Oct. 23, 2012]

§ 524.1044d Gentamicin and betamethasone ointment.

(a) *Specifications*. Each gram of ointment contains gentamicin sulfate equivalent to 3 milligrams of gentamicin base and betamethasone valerate equivalent to 1 milligram of betamethasone.

(b) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*—(i) *Otitis externa*. Instill 3 to 8 drops into the ear canal twice daily for 7 days.

(ii) *Infected superficial lesions*. Apply to cover the treatment area twice daily for 7 to 14 days.

(2) *Indications for use*. For the treatment of acute and chronic otitis externa and infected superficial lesions caused by bacteria sensitive to gentamicin.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[47 FR 26378, June 18, 1982, as amended at 52 FR 7832, Mar. 13, 1987; 79 FR 10969, Feb. 27, 2014]

§ 524.1044e Gentamicin spray.

(a) *Specification*. Each milliliter of sterile aqueous solution contains gentamicin sulfate equivalent to 1.07 milligrams of gentamicin.

(b) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in cattle*—(1) *Amount*. Hold the sprayer upright 3 to 6 inches from the affected eye, with the opening directed towards the eye, and pump once. Treat once daily for up to 3 days.

(2) *Indications for use*. For the treatment of pinkeye in cattle (infectious bovine keratoconjunctivitis) caused by *Moraxella bovis*.

(3) *Limitations*. Conditions other than bacterial infections of the bovine eye and infectious keratoconjunctivitis caused by *Moraxella bovis* may produce similar signs. If conditions persists or

increases, discontinue use and consult a veterinarian.

[48 FR 41157, Sept. 14, 1983, as amended 52 FR 7833, Mar. 13, 1987; 79 FR 10969, Feb. 27, 2014]

§ 524.1044f Gentamicin and betamethasone spray.

(a) *Specifications*. Each milliliter of spray contains gentamicin sulfate equivalent to 0.57 milligram (mg) gentamicin base and betamethasone valerate equivalent to 0.284 mg betamethasone.

(b) *Sponsors*. See Nos. 000061, 054925, 058005, 058829, and 065531 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. Hold bottle upright 3 to 6 inches from the lesion and depress the sprayer head twice. Administer two spray actuations two to four times daily for 7 days.

(2) *Indications for use*. For the treatment of infected superficial lesions caused by bacteria susceptible to gentamicin.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[71 FR 13542, Mar. 16, 2006, as amended at 72 FR 5929, Feb. 8, 2007; 74 FR 22822, May 15, 2009; 77 FR 3598, Jan. 25, 2012]

§ 524.1044g Gentamicin, betamethasone, and clotrimazole ointment.

(a) *Specifications*. Each gram (g) of ointment contains gentamicin sulfate equivalent to 3 milligrams (mg) gentamicin base, betamethasone valerate equivalent to 1 mg betamethasone, and 10 mg clotrimazole.

(b) *Sponsors*. See sponsors in § 510.600(c) of this chapter for uses as in paragraph (c) of this section.

(1) No. 000061 for use of 7.5- or 15-gram tubes, 12.5-, 30-, or 215-g bottles.

(2) No. 054925 for use of 7.5- or 15-g tubes; 10-, 15-, 25-, or 215-g bottles.

(3) No. 000859 for use of 10-, 20-, 40-, or 215-g bottles.

(4) No. 025463 for use of 7.5- or 15-g tubes, or 215-g bottles.

(c) *Conditions of use in dogs*—(1) *Amount*. Instill ointment twice daily into the ear canal for 7 consecutive days.